

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

UNIMED PHARMACEUTICALS, LLC,  
BESINS HEALTHCARE INC., and BESINS  
HEALTHCARE LUXEMBOURG SARL,

Plaintiffs,

v.

PERRIGO COMPANY, and PERRIGO  
ISRAEL PHARMACEUTICALS LTD.,

Defendants.


Civil Action No. 13-236-RGA

MEMORANDUM OPINION

Calvin Griffith (argued), Esq., Jones Day, Cleveland, OH; Kenneth Canfield, Esq., Jones Day, New York, NY; Jason Winchester, Esq., Jones Day, Chicago, IL; Mary Graham, Esq., Morris Nichols, Arsht & Tunnell LLP, Wilmington, DE; attorneys for Plaintiffs.

William Rakoczy (argued), Esq., Rakoczy Molino Mazzochi Siwik LLP, Chicago, IL; Gregory Duff, Esq., Rakoczy Molino Mazzochi Siwik LLP, Chicago, IL; Alice Riechers, Esq., Rakoczy Molino Mazzochi Siwik LLP, Chicago, IL; Lauren Dunne, Esq., Rakoczy Molino Mazzochi Siwik LLP, Chicago, IL; Megan C. Haney, Esq., Phillips, Goldman & Spence, P.A., Wilmington, DE; attorneys for Defendants.

March 11, 2015

  
ANDREWS, U.S. DISTRICT JUDGE:

Plaintiffs assert that Defendants' ANDAs infringe Plaintiffs' patents. Before this Court is the issue of claim construction of disputed terms found in nine patents: U.S. Patent No. 6,503,894 ("the '894 patent"); four patents collectively called the "Malladi Patents," U.S. Patent Nos. 8,466,136 ("the '136 patent"), 8,466,137 ("the '137 patent"), 8,466,138 ("the '138 patent"), and 8,486,925 ("the 925 patent"); and four patents collectively called the "New Malladi Patents," U.S. Patent Nos. 8,729,057 ("the '057 patent"), 8,741,881 ("the '881 patent"), 8,754,070 ("the '070 patent"), and 8,759,329 ("the '329 patent").

The Court has considered the parties' claim construction briefing (D.I. 227, 228, 229, 230, 231) and held a *Markman* hearing. (D.I. 238).

## **I. LEGAL STANDARD**

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). "[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at \*1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (internal quotation marks and citations omitted).

“[T]he words of a claim are generally given their ordinary and customary meaning. . . . [Which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Phillips*, 415 F.3d at 1312–13 (internal quotation marks and citations omitted). “[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent.” *Id.* at 1321 (internal quotation marks omitted). “In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.” *Id.* at 1314 (internal citations omitted).

When a court relies solely upon the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court’s construction is a determination of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The court may also make factual findings based upon consideration of extrinsic evidence, which “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Phillips*, 415 F.3d at 1317–19 (internal quotation marks and citations omitted). Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

“A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent.” *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that “a claim interpretation that would

exclude the inventor's device is rarely the correct interpretation." *Osram GmbH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (internal quotation marks and citation omitted).

## **II. AGREED UPON CONSTRUCTIONS**

The parties have requested that the Court adopt several agreed upon constructions (D.I. 227 at p. 10), which it does:

### **A. The '894 patent**

1. "about" (Claims 31, 35, and 38-41)
  - a. *Construction*: "approximately"
2. "pharmaceutical composition" (Claim 31)
  - a. *Construction*: "A composition intended for a pharmaceutical use"

### **B. Malladi Patents**

1. "about" ('137 patent, claims 4-5; '138 patent, claims 4-5)
  - a. *Construction*: "approximately"
2. "ethanol" ('136 patent, claim 1; '137 patent, claim 1; '138 patent, claim 1; '925 patent, claim 1 )
  - a. *Construction*: "C<sub>2</sub>H<sub>5</sub>OH, such as dehydrated alcohol USP, alcohol USP, or any common form including in combination with various amounts of water"

### **C. New Malladi Patents**

1. "about" ('881 patent, claims 13, 23, 26, 29; '329 patent, claim 18)
  - a. *Construction*: "approximately"

2. “absolute ethanol” (‘057 patent, claims 3, 10-11; ‘881 patent, claims 3, 9-10, 15-16; ‘070 patent, claims 1, 6-7; ‘329 patent, claims 3, 9, 13, 16)

a. *Construction*: “C<sub>2</sub>H<sub>5</sub>OH”

3. “ethanol” (‘057 patent, claims 1-3; ‘881 patent, claims 1-3; ‘329 patent, claims 1-3)<sup>1</sup>

a. *Construction*: “C<sub>2</sub>H<sub>5</sub>OH, such as dehydrated alcohol USP, alcohol USP, or any common form including in combination with various amounts of water”

### III. CONSTRUCTION OF DISPUTED TERMS

#### A. The ‘894 Patent

Claim 31 of the ‘894 patent is representative:

A method for administering an active agent to a human subject in need thereof, the method comprising:

- a. providing a pharmaceutical composition *consisting essentially of*:
  - (i) about 0.5% to about 5% testosterone;
  - (ii) about 0.1% to about 5% isopropyl myristate;
  - (iii) about 30% to about 98% of an alcohol selected from the group consisting of *ethanol* and isopropanol; and
  - (iv) about 0.1% to about 5% of a *gelling agent*;wherein the percentages are weight to weight of the composition; and
- b. applying a daily dose of the composition to skin of the subject in an amount sufficient for the testosterone to reach the bloodstream of the subject wherein serum concentration is substantially maintained between about 400 ng testosterone per dl serum to about 1050 ng testosterone per dl serum for at least 24 hours after the subject has applied the daily dose of the composition for at least 2 consecutive days.

---

<sup>1</sup> The Amended Joint Claim Construction Brief applies this so-called agreed-upon construction of “ethanol” to several other claims from these, and other, patents. Defendants, however, objected, stating they only agreed to construe “ethanol” as such in claims 1-3 of the ‘057, ‘881, and ‘329 patents. (D.I. 227 at p. 10). The Court will only adopt the agreed-upon reading of “ethanol” for the claims listed here because these appear to be all to which Defendants have actually agreed.

(‘894 patent, claim 31) (disputed claim construction terms emphasized).

1. “consisting essentially of” (claim 31)

a. *Plaintiffs’ proposed construction*: “The invention covers products containing the specified ingredients as well as products containing unspecified ingredients, provided that the unspecified ingredients do not materially affect the basic and novel properties of the claimed invention.”

b. *Defendants’ proposed construction*: “Claim covers products made from the designated ingredients and any additional ingredients that do not materially affect any alleged basic and novel characteristics of the claimed subject matter.”

c. *Court’s construction*: “Claim covers products made from the designated ingredients and any additional ingredients that do not materially affect any alleged basic and novel characteristics of the claimed subject matter.”

The dispute between the parties boils down to whether the claims say that the products contain certain ingredients, or are made from those ingredients. (D.I. 227 at pp. 12-19). As Plaintiffs have said, “[t]his may be a distinction without a difference.” (*Id.* at p. 12). Plaintiffs cite several examples of language in other claims and the specification that apparently demonstrate that this claim should be read as describing only the ingredients in the final product. (*Id.* at p. 14). Despite what Plaintiffs say, the Court is not so sure that the Federal Circuit case cited by Plaintiffs really resolves the “contain,” as opposed to “made from,” distinction. Instead the case law demonstrates only that the ingredients must be included, but not necessarily at what point they must be included. (*Id.* at p. 12; *see PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998) (“Typically, ‘consisting essentially of’ precedes a list of ingredients in a composition claim or a series of steps in a process claim. By using the term ‘consisting

essentially of,' the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. A 'consisting essentially of' claim occupies a middle ground between closed claims that are written in a 'consisting of' format and fully open claims that are drafted in a 'comprising' format.")). Plaintiffs say that they are concerned that the Defendants are restricting the claim to the starting ingredients, "with no consideration of the final product." (*Id.* at p. 12). Defendants indeed argue that the claims should be read as a list of ingredients from which that final product is made. (*Id.* at p. 15).

The Court agrees with Defendants. The Court is particularly persuaded by Defendants' argument that certain ingredients such as 0.1 N sodium hydroxide, required by other claims, are not necessarily present in the final composition despite the same "consisting essentially of" language.<sup>2</sup> (*Id.* at p. 15). Therefore, it cannot be the case that "consisting essentially of" describes what the final product contains, not what it was made from, if certain ingredients are not present in the final product. Plaintiffs do not appear to rebut this argument. The specification, as Defendants argue, also lists specific ingredients from which the composition is made, for example, in Table 5. (*Id.* at p. 16; '894 patent at 13:16-35). Even Plaintiffs' expert Dr.

---

<sup>2</sup> It is true, as Plaintiffs argue, that claim 31 does not require 0.1 N sodium hydroxide, which is instead required by claim 1. (D.I. 227 at p. 21 ("Defendants fail to identify any element of claim 31 that cannot be both an ingredient used to make the formulation and also be contained in the final composition.")). But claim 1 still has the "consisting essentially of" language, and the term must be interpreted consistently throughout the patent, in claim 1 and claim 31, absent some evidence to the contrary. Plaintiffs, however, provide no evidence for reading this same term differently in different claims. Therefore, the fact that claim 1 requires an ingredient such as 0.1 N sodium hydroxide that is not present in the final product informs how "consisting essentially of" should be construed in claim 31.

Weiner appeared to opine that the '894 patent covers the components "used to make the composition." (*Id.* at p. 17).

Therefore, "consisting essentially of," in the context of the patent, describes the ingredients the composition is made from, not those it contains.

2. "gelling agent" (claim 31)

- a. *Plaintiffs' proposed construction*: "a thickener"
- b. *Defendants' proposed construction*: "An agent capable of gelling"
- c. *Court's construction*: "An agent capable of gelling"

The crux of Plaintiffs' argument is that the terms "thickener" and "gelling agent" were used synonymously in the specification and the claims of the '894 patent. (D.I. 227 at p. 27). In response, Defendants argue that a gelling agent must mean an agent that is capable of, but has not yet, gelled, drawing from the patent's specific identification of carboxymethylcellulose and polyacrylic acid. (*Id.* at p. 29). Defendants also argue that a gelling agent cannot include both a polyacrylic acid and sodium hydroxide (or another neutralizing agent). (*Id.* at pp. 29-32). Plaintiffs dispute these points, arguing that Defendants' two central points are "extra baggage" and a "tacit summary judgment argument." (*Id.* at p. 34). The Court is not persuaded by the argument, even if true, that because "thickener" and "gelling agent" were used synonymously during prosecution history they are interchangeable at the claim construction phrase. It seems clear that "thickener" is a broader term than "gelling agent." Flour and cornstarch are "thickeners," but are they "gelling agents"? The Court adopts "an agent capable of gelling," the plain and ordinary meaning of gelling agent, as its construction. While the Court adopts Defendants' construction, it is not convinced that the construction is any different than the plain



and ordinary meaning of gelling agent. The Court believes its construction of “gelling agent” is consistent with the construction of “consisting essentially of.”<sup>3</sup>

3. “Ethanol” (claim 31)

a. *Plaintiffs’ proposed construction:* “C<sub>2</sub>H<sub>5</sub>OH in the form of dehydrated alcohol USP, alcohol USP, or in any common form including in combination with various amounts of water.”

b. *Defendants’ proposed construction:* “C<sub>2</sub>H<sub>5</sub>OH”

c. *Court’s construction:* “C<sub>2</sub>H<sub>5</sub>OH in the form of dehydrated alcohol USP, alcohol USP, or in any common form including in combination with various amounts of water.”

The dispute over the construction of this term centers on whether ethanol refers to pure ethanol or a form of ethanol that is combined with water. Plaintiffs’ strongest arguments for its construction are that the specification and other claims refer to ethanol combined with water. (D.I. 227 at p. 40). For example, Table 5 of the specification, describing one embodiment of the testosterone gel, includes the ingredient “Ethanol (95% w/w),” meaning 95% ethanol and 5% water by weight. (‘894 patent at 13:16-35). Defendants respond that at the time of patenting, a person of ordinary skill would understand ethanol means only “C<sub>2</sub>H<sub>5</sub>OH,” a position Plaintiffs dispute. (D.I. 227 at pp. 39-42). Plaintiffs rightly point out that Defendants’ approach would read out the patent’s preferred embodiment, which uses a combination of ethanol and water. (*Id.* at p. 47; see *Globetrotter Software, Inc. v. Elan Computer Grp., Inc.*, 362 F.3d 1367, 1381 (Fed.

---

<sup>3</sup> Whether a particular substance is or is not a gelling agent is an issue for trial. The specification and the claims seem to make clear that Carbopol 980 is a gelling agent. (‘894 patent, Table 5; 12:60-64). If Carbopol 980 requires sodium hydroxide to gel, that does not necessarily make sodium hydroxide a gelling agent.

Cir. 2004) (“A claim interpretation that excludes a preferred embodiment from the scope of the claim is rarely, if ever, correct.”) (internal quotation marks omitted) (citations omitted)). Further, it does not seem to be a coincidence that dependent claims 22 and 35 limit the “alcohol” to 72.5%, which corresponds to Table 5’s reference to “Ethanol (95% w/w)” as constituting 72.5% of the described embodiment. Therefore, it does not make sense to read ethanol as Defendants do, and Plaintiffs’ construction is adopted.

## **B. Malladi Patents**

Claim 1 of the ‘136 patent is representative of the claims in the Malladi Patents:

*A hydroalcoholic gel consisting of:*

- a) 1.3% to 1.7% (w/w) testosterone;
- b) 0.9% to 1.0% (w/w) isopropyl myristate;
- c) 67.0% to 74.0% (w/w) of a lower alcohol selected from the group consisting of: methanol, ethanol, n-propanol, isopropanol, n-butanol, isobutanol, sec-butanol and tert-butanol;
- d) 0.6% to 1.4% (w/w) of a polyacrylic acid;
- e) 1.0% to 10.0% (w/w) of 0.1 N sodium hydroxide; and
- f) water.

(‘136 patent, claim 1) (disputed claim construction terms emphasized).

### **1. “hydroalcoholic gel consisting of” (‘136 patent, claim 1)**

a. *Plaintiffs’ proposed construction:* “‘hydroalcoholic gel’ means ‘a gel employing water and alcohol.’ The term ‘consisting of’ means that the invention covers products that contain the ingredients listed in the claim as well as elements unrelated to the invention and unavoidable impurities.”

b. *Defendants’ proposed construction:* “Gel employing water and alcohol made from the designated ingredients and excluding any element, step or ingredient not designated in the claim.”

c. *Court's construction*: "Gel employing water and alcohol made from the designated ingredients and excluding any element, step or ingredient not designated in the claim."

Because the parties basically agree that "hydroalcoholic gel" means a "gel employing water and alcohol," the material dispute is the meaning of "consisting of." (D.I. 227 at p. 50). The parties' disagreement is about whether the transitional phrase means a composition is "made from," or "contains" certain ingredients. In my opinion, the term again reflects a composition that must be made from certain ingredients.

Plaintiffs are correct that the term of art "consisting of" restricts the scope of a claim from including "materials other than those recited except for impurities ordinarily associated therewith." *See Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1360 (Fed. Cir. 2006) (internal quotation marks omitted) (citations omitted). As Plaintiffs note, the Federal Circuit has said that, nonetheless, "'consisting of' does not exclude additional components or steps that are unrelated to the invention." *Id.* (citations omitted). It is unclear where this argument gets Plaintiffs. "Consisting of" allows limited impurities or substances unrelated to the invention—it does not establish whether the hydroalcoholic gel contains or is made from certain ingredients.

The Court finds Defendants' arguments persuasive, for largely the same reasons it did for the earlier "consisting essentially of" term. Defendants broadly argue that the Malladi Patents, like the '894 patent,<sup>4</sup> include ingredients such as "0.1 N sodium hydroxide," which are not present after the composition is mixed. (D.I. 227 at p. 53). Therefore, "consisting of" must describe the ingredients the product is made from, not those it contains as a finished product.

---

<sup>4</sup> The '894 patent is extrinsic evidence to the Malladi and New Malladi Patents.

Defendants also provide citations to the specifications' use of lists of ingredients to "yield" various formulations. (*Id.* at p. 54; *see, e.g.*, '136 patent at 26:44-59). Again, Defendants draw attention to extrinsic evidence demonstrating that "consisting of" describes what the composition is made from, including Plaintiffs' expert Dr. Weiner. (D.I. 227 at p. 56). Plaintiffs' responses to these arguments are not especially compelling. While Plaintiffs agree that the "0.1 N sodium hydroxide" ingredient does not keep its normality once mixed, Plaintiffs argue that the composition still contains the hydroxide solution. (*Id.* at p. 59). That could very well be the case. But the fact that the Plaintiffs concede that the particular ingredient "0.1 N sodium hydroxide"—with that particular normality—is only present before the composition is mixed supports the argument that these ingredients in the claim are what the composition is "made from," not a description of ingredients the composition contains in its final form. Plaintiffs also stress that the emphasis of the patent is on the formulation, rather than the method of making this formulation. (*Id.* at p. 59). The Court does not necessarily disagree with that assertion, because this is not a process patent, but the statement does not really help resolve the made from or contain dispute.

For the above reasons, the Court adopts Defendants' construction.

2. "1.0% to 10.0% (w/w) of 0.1 N sodium hydroxide" ('136 patent, claim 1; '137 patent claim 1)

a. *Plaintiffs' proposed construction*: "The amount of sodium hydroxide in 1.0% to 10.0% (w/w) of a 0.1 N sodium hydroxide solution."

b. *Defendants' proposed construction*: "Exactly 1.0% to 10.0% (w/w) of 0.1 N aqueous solution of sodium hydroxide."

c. *Court's construction:* "1.0% to 10.0% (w/w) of 0.1 N aqueous solution of sodium hydroxide."

Plaintiffs broadly argue that that this term refers to the "amount" of sodium hydroxide in the claimed formulation. (D.I. 227 at pp. 61-62). Because normality conveys mass of solid sodium hydroxide dissolved in a given amount of water, Plaintiffs argue one of ordinary skill would recognize that using "0.1 N" is "simply a way of expressing the amount of pure sodium hydroxide in the Malladi Patent formulations." (*Id.* at p. 62). Plaintiffs further state: "In other words, 1.0% to 10.0% (w/w) 0.1 N sodium hydroxide solution requires that every 100 grams of recited gel contain between 0.004 grams and 0.040 grams of pure sodium hydroxide." (*Id.*). Defendants rightfully argue that this reading would result in "*any amount of any normality of sodium hydroxide solution*" that results in the stated amount of pure sodium hydroxide. (*Id.* at p. 64) (emphasis in original). The Court agrees. As Defendants argue, Plaintiffs' approach reads out the "1.0% to 10.0% (w/w)" and "0.1 N" limitations from the claims. (*Id.*).

Plaintiffs point to the Malladi Patents' specification, which contemplates other normalities for sodium hydroxide, but the Court is not so sure that that "demonstrates that the precise normality is immaterial." (*Id.* at p. 62). The Malladi Patents' specifications do describe a "further embodiment" where the formulation has "an aqueous solution of sodium hydroxide such as 0.1 N sodium hydroxide, or 1.5 N sodium hydroxide, or 2.0 N sodium hydroxide or any other convenient strength aqueous solution in an amount sufficient to form a gel." ('136 patent at 5:40-43). The next sentence in the specification reads, however, "In one embodiment, the composition was prepared using between about 1.0% and 10.0% 0.1 N sodium hydroxide." It appears that the specification provided formulations that were not eventually in the claims, with the exception of the embodiment of using between "about 1.0% and 10.0% 0.1 N sodium

hydroxide.” Even if that were not the case, the fact that the specification lists different normalities for sodium hydroxide so explicitly – 0.1 N, 1.5 N, or 2.0 N – is evidence that one skilled in the art would attach meaning to a term in a claim that expresses normality, such as 0.1 N. Therefore, it could not be the case that, as Plaintiffs argue, normality is simply immaterial. Defendants provide other evidence for their position, including prosecution history. Defendants argue that Plaintiffs disclaimed “sodium hydroxide” generally for 0.1 N sodium hydroxide. (D.I. 227 at p. 68). The Court is not so sure that the prosecution history disclaimer is that clear, but in any case, the patent itself supports Defendants’ position.

While the Court believes Defendants’ position is generally correct, the preface to the construction of “exactly” is unnecessary and needlessly adds a limitation. The Court is not certain what “exactly” adds that is not captured in the rest of the construction. Defendants do not seem to offer a reason to include “exactly” in the briefing, and there does not seem to be any reason why this limitation should be added.

Therefore, the Court adopts the construction of “1.0% to 10.0% (w/w) of 0.1 N aqueous solution of sodium hydroxide.”

3. “7.0% (w/w) 0.1 N sodium hydroxide” – ‘138 and ‘925 patents (claims 1, 3); “The amount of the .01 N sodium hydroxide is 7.0% (w/w)” – ‘136 patent (claim 3); “The 0.1 N sodium hydroxide is in an amount of 7.0% (w/w)” – ‘137 patent (claim 3).

a. *Plaintiffs’ proposed construction:* “The amount of sodium hydroxide in 7% (w/w) of a 0.1 N sodium hydroxide solution.”

b. *Defendants’ proposed construction:* “Exactly 7% (w/w) of 0.1 N aqueous solution of sodium hydroxide.”

c. *Court's construction:* "7% (w/w) of 0.1 N aqueous solution of sodium hydroxide."

Both parties rely on their same analysis and reasons for these terms as they did for the construction of the term "1.0% to 10.0% (w/w) of 0.1 N sodium hydroxide." (D.I. 227 at pp. 78-79). Likewise, the Court relies on its same analysis for this term. Accordingly, the Court, for the same reasons as above, will construe this term as "7% (w/w) of 0.1 N aqueous solution of sodium hydroxide."

4. "0.1 N sodium hydroxide" – '136, '137, '138, and '925 patents (claims 1, 3)

a. *Plaintiffs' proposed construction:* This term should not be construed in isolation but rather should be construed in the context of the entire claim limitation.

b. *Defendants' proposed construction:* "0.1 N aqueous solution of sodium hydroxide."

c. *Court's construction:* This term is not construed in isolation but rather is construed in the context of the entire claim limitation.

It is unclear why the Defendants would like this term to be construed separately from the other phrases that contain it. The Court has essentially agreed with construing "0.1 N sodium hydroxide" as "0.1 N aqueous solution of sodium hydroxide" within the context of larger terms where sodium hydroxide is in a water solution. Defendants appear to be concerned that Plaintiffs will ignore that the solution must be aqueous. In view of the Court's construction of the larger terms, it is unnecessary to construe "0.1 N sodium hydroxide" standing alone. Therefore, the Court need not and will not construe this term in isolation.

### **C. New Malladi Patents**

Claim 1 of the '057 patent is representative of the claims in the New Malladi Patents:

A gel pharmaceutical *composition consisting of*:

- a) 1.3% to 1.7% (w/w) testosterone;
- b) 0.9% to 1.0% (w/w) isopropyl myristate;
- c) 67.0% to 74.0% (w/w) of a lower alcohol selected from the group consisting of methanol, ethanol, n-propanol, isopropanol, n-butanol, isobutanol, sec-butanol, and tert-butanol;
- d) 0.6% to 1.4% (w/w) of a *gelling agent*, which gelling agent is an anionic polymer that has been neutralized with an amount of neutralizer sufficient to form a gel; and
- e) water.

('057 patent, claim 1) (disputed claim construction terms emphasized).

1. "composition consisting of" – '057 patent (claim 1), '881 patent (claims 1, 14) and '070 patent (claim 1); "composition [...] consists of" – '057 patent (claims 10, 11), '881 patent (claims 9, 10, 15, 16); and '070 patent (claims 6, 7).

a. *Plaintiffs' proposed construction*: The terms "consisting of" and "consists of" mean that the invention covers products that contain the ingredients listed in the claim as well as elements unrelated to the invention and unavoidable impurities.

b. *Defendants' proposed construction*: "composition made from the designated ingredients and excluding any element, step, or ingredient not designated in the claim."

c. *Court's construction*: "composition containing the designated ingredients and excluding any ingredient not designated in the claim other than elements unrelated to the invention and unavoidable impurities."

The debate between the parties again broadly focuses on whether the composition is made from or contains certain ingredients. Or, as Plaintiffs characterize it, the parties disagree about whether the terms: "(1) allow for consideration of the components in the final accused composition; and (2) allow the final composition to contain elements unrelated to the invention



and unavoidable impurities. Plaintiffs say yes to both; Defendants say no.” (D.I. 227 at p. 83). Plaintiffs broadly argue that the intrinsic evidence supports such a reading because the claim language does not say “made from,” only “composition consisting of.” (*Id.* at pp. 84-85).

Plaintiffs point to the ‘329 patent, one in the New Malladi series, which claims “gel pharmaceutical composition[s] obtained by combining the following ingredients which consist of” certain ingredients, while the other New Malladi patents instead use the term “composition consisting of.” (*Id.*). Plaintiffs argue that the fact that the ‘329 patent uses “obtained by combining,” meaning that the product is made with certain ingredients, implies that “composition consisting of” in the other New Malladi patents must describe what the product contains, not what it is made with. (*Id.*). The Court agrees.

There is evidence and argument that supports both parties’ positions, but Plaintiffs’ position is more persuasive. The “obtained by combining” term in the ‘329 patent demonstrates that the “composition consisting of” term, and its variants, in the ‘058, ‘881, and ‘070 patents must mean something different. Plaintiffs argue that claim differentiation principles apply when related patents use different terms, as is the case with the ‘329 patent’s use of a different term. (*Id.* at p. 93). Defendants argue that “obtained by combining” was used interchangeably with “consisting of” during prosecution and elsewhere. (*Id.* at p. 89). The Court does not find that record to be as unequivocal as Defendants make it out to be. Plaintiffs say that the ‘329 patent is a formulation patent, while the ‘057 and ‘070 patents claim compositions, and the ‘881 patent claims methods. (*Id.* at pp. 93-94). The fact that the list of ingredients is similar, but not identical, in the different patents might suggest that “obtained by combining” should be treated differently than “composition consisting of.” *See, e.g.*, ‘057 patent, claim 1; ‘329 patent, claim 1. Even still, it is difficult to cleanly compare the terms in the ‘329 patent with these in the other

New Malladi patents because the '329 patent claims different ingredients. *Compare, e.g.,* '057 patent, claim 1 ("0.6% to 1.4% (w/w) of a gelling agent, which gelling agent is an anionic polymer that has been neutralized with an amount of neutralizer sufficient to form a gel"); *with* '329 patent, claim 1 ("0.6% to 1.4% (w/w) of a gelling agent which is a polyacrylic acid; . . . an amount of a neutralizer of the polyacrylic acid sufficient to form a gel"); '070 patent, claim 1 ("68.1% (w/w) absolute ethanol"); *with* '329 patent, claim 13 ("68.1% (w/w) absolute ethanol or 73.5% (w/w) of 95% (v/v) of ethanol"). Therefore, contrary to what Defendants argue, the phrase "composition consisting of" should not be given the same meaning as "composition obtained by combining the following ingredients which consist of."

The analysis of this term in the New Malladi patents need not have an effect on how similar terms were construed in the earlier-filed Malladi and '894 patents. The timeline of events requires treating the later-filed New Malladi patents differently. The original complaint for this action was filed on February 15, 2013 asserting only infringement of the '894 patent. (D.I. 1). The Malladi patents were filed in July and October of 2011, and issued in June and July of 2013. The complaint was amended on October 8, 2013 to include infringement of the Malladi patents. (D.I. 30). The New Malladi patents were all filed on March 14, 2013, and issued in May and June of 2014. The complaint was again amended on August 20, 2014 to include infringement of the New Malladi patents. (D.I. 164). Because the New Malladi patents were only filed after litigation had already started, I believe their value in construing terms in the earlier-filed patents should be discounted. *See ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1376 (Fed.Cir. 2009) (agreeing with a district court that gave less weight to a claim added years after filing); *see also Biogen, Inc. v. Berlex Labs., Inc.*, 318 F.3d 1132, 1140 (Fed. Cir. 2003)

(“Representations during prosecution cannot enlarge the content of the specification, and the district court was correct in relying on the specification in analyzing the claims.”).

Therefore, the Court construes the terms “composition consisting of” and “composition [...] consists of” as meaning “composition containing the designated ingredients and excluding any ingredient not designated in the claim other than elements unrelated to the invention and unavoidable impurities.”

2. “gel pharmaceutical composition [...] obtained by combining the following ingredients which consist of” (Claims 1, 9, 13, 16—‘329 patent).

a. *Plaintiffs’ proposed construction*: “gel pharmaceutical composition [...] made from the listed ingredients” as well as elements unrelated to the invention and unavoidable impurities

b. *Defendants’ proposed construction*: “gel pharmaceutical composition [...] made from the designated ingredients and excluding any element, step, or ingredient not designated in the claim”

c. *Court’s construction*: “gel pharmaceutical composition [...] made from the designated ingredients and excluding any element, step, or ingredient not designated in the claim other than elements unrelated to the invention and unavoidable impurities”

The parties make generally the same arguments as they have made throughout the briefing. This time, however, there is no argument about whether the ‘329 composition is limited to those “made from” certain ingredients. (D.I. 227 at p. 86). The dispute between the parties is about whether “the final product can also contain elements unrelated to the invention and unavoidable impurities,” as Plaintiffs explain. (*Id.* at p. 86). Plaintiffs make much of how

this language of “composition ... obtained by combining the following ingredients which consist of” is or is not different from the “consist of” language in the earlier patents. (*Id.* at pp. 91-92). As mentioned previously, it is challenging to draw much from these cross-patent comparisons of language without providing more evidence about why the language was different, which Plaintiffs have not done.

As the Federal Circuit has explained, “[t]he phrase ‘consisting of’ is a term of art in patent law signifying restriction and exclusion, while, in contrast, the term ‘comprising’ indicates an open-ended construction. In simple terms, a drafter uses the phrase ‘consisting of’ to mean ‘I claim what follows and nothing else.’” *Vehicular Technologies Corp. v. Titan Wheel Int’l, Inc.*, 212 F.3d 1377, 1382-83 (Fed. Cir. 2000) (citations omitted). Nonetheless, the Federal Circuit has explained that “while ‘consisting of’ limits the claimed invention, it does not limit aspects unrelated to the invention.” *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331 (Fed. Cir. 2004). Likewise, the Federal Circuit has held that “impurities that a person of ordinary skill in the relevant art would ordinarily associate with a component on the ‘consisting of’ list do not exclude the accused product or process from infringement.” *Conoco, Inc. v. Energy & Env’tl. Int’l, L.C.*, 460 F.3d 1349, 1360 (Fed. Cir. 2006). In light of this case law, Plaintiffs argue for a construction that includes these two exceptions for elements unrelated to the invention or certain impurities. (D.I. 227 at p. 92). Defendants state that the exceptions are irrelevant. (*Id.* at p. 95). This seems a concession that the exceptions are rightfully an appropriate construction. If the exceptions turn out to be irrelevant, they are irrelevant. But that does not make them erroneous.

The Court adopts the construction “gel pharmaceutical composition [...] made from the designated ingredients and excluding any element, step, or ingredient not designated in the claim other than elements unrelated to the invention and unavoidable impurities.”

3. “[T]he amount of sodium hydroxide is in the range of 1.0% to 10% (w/w) of 0.1 N sodium hydroxide”—‘057 patent (claim 12) and ‘329 patent (claims 10, 16)

a. *Plaintiffs’ proposed construction*: “the amount of sodium hydroxide is the amount present in 1.0% to 10.0% (w/w) of a 0.1 N sodium hydroxide solution”

b. *Defendants’ proposed construction*: “the composition is made from exactly 1.0% to 10% (w/w) of 0.1 N aqueous solution of sodium hydroxide”

c. *Court’s construction*: “the composition is made from 1.0% to 10% (w/w) of 0.1 N aqueous solution of sodium hydroxide”

The arguments for these terms repeat those previously made for other similar terms. For the same reasons discussed earlier, the Court reaches the same conclusions. Therefore, the Court adopts the construction “the composition is made from 1.0% to 10% (w/w) of 0.1 N aqueous solution of sodium hydroxide.”

4. “0.1 N sodium hydroxide”—‘057 patent (claim 12) and ‘329 patent (claims 10, 16, 18)

a. *Plaintiffs’ proposed construction*: The term should be construed only as part of the larger phrase “the amount of sodium hydroxide is in the range of 1.0% to 10% (w/w) of 0.1 N sodium hydroxide.”

b. *Defendants’ proposed construction*: “0.1 N aqueous solution of sodium hydroxide”

c. *Court's construction:* The term is construed only as part of the larger phrase "the amount of sodium hydroxide is in the range of 1.0% to 10% (w/w) of 0.1 N sodium hydroxide."

For the reasons mentioned previously, the Court will not construe this term separately from its larger context.

5. "gelling agent"—'057 patent (claim 1); '881 patent (claims 1, 14); '070 patent (claim 1); '329 patent (claims 1, 13)

a. *Plaintiffs' proposed construction:* "a thickener"

b. *Defendants' proposed construction:* "a thickening agent, including an anionic polymer or a neutralized anionic polymer"

c. *Court's construction:* "a thickening agent"

The Court adopts "a thickening agent," which essentially is what both parties propose for these patents.<sup>5</sup> Plaintiffs note that each disputed use of "gelling agent" in the New Malladi Patents is followed by a particular type of gelling agent, which is an anionic polymer in patents '057, '881 and '070, but a polyacrylic acid in the '329 patent. *See* D.I. 227 at p. 111; *see e.g.*, '057 patent at claim 1 ("0.6% to 1.4% (w/w) of a gelling agent, which gelling agent is an anionic polymer that has been neutralized with an amount of neutralizer sufficient to form a gel").

---

<sup>5</sup> The Court notes that the proposal is different than what Defendants proposed for the '894 patent, but also notes that "gelling agent" is limited in each of the New Malladi Patents in ways in which it is not limited in the '894 patent. For example, claim 31 of the '894 patent simply refers to a "gelling agent," while claims 1 of the '057, 881, and '070 patents refer to a "gelling agent, which gelling agent is an anionic polymer" and claim 1 of the '329 patent refers to a "gelling agent which is a polyacrylic acid." *Compare* '829 patent, claim 1 *with* claims 1 of '057 patent, '881 patent, '070 patent and '329 patent.

Therefore, Plaintiffs argue that Defendants' restating the type of gelling agent in the construction is unnecessary and redundant. The Court agrees.

Therefore, the Court adopts "a thickening agent" as its construction of "gelling agent" in the New Malladi patents.

6. "dehydrated ethanol" — '881 patent (claim 14)

a. *Plaintiffs' proposed construction*: "C<sub>2</sub>H<sub>5</sub>OH in the form of dehydrated alcohol USP, which contains not less than 99.2% by weight or 99.5% by volume of C<sub>2</sub>H<sub>5</sub>OH"

b. *Defendants' proposed construction*: "C<sub>2</sub>H<sub>5</sub>OH"

c. *Court's construction*: "C<sub>2</sub>H<sub>5</sub>OH in the form of dehydrated alcohol USP, which contains not less than 99.2% by weight or 99.5% by volume of C<sub>2</sub>H<sub>5</sub>OH"

Plaintiffs argue that "dehydrated ethanol," which only appears in the '881 patent, must be construed differently than "absolute ethanol," which appears in all of the New Malladi Patents, including the '881 patent. (D.I. 227 at pp.115-16; *see also* '881 patent claim 14 and 15). Defendants seem to argue that both "absolute ethanol" and "dehydrated ethanol" mean C<sub>2</sub>H<sub>5</sub>OH because the patentee used the two terms interchangeably, a position for which Defendant provides scant evidence. (D.I. 227 at p. 117). The Court finds Defendants' reasoning unpersuasive and that the two terms must have distinct meanings, especially because they appear in consecutive claims in the '881 patent, in enumerated lists of precise ingredients in particular compositions. It seems highly implausible that even the sloppiest patent drafter could list "absolute ethanol" and "dehydrated ethanol" in two consecutive claims, intending them to be interchangeable, as Defendants posit. *See, e.g.*, '881 patent at claim 14 and 15. The Court is also persuaded by Plaintiffs' argument that the specification clarifies that dehydrated ethanol

refers to dehydrated ethanol USP, which provides that dehydrated alcohol contain not less than 99.2% by weight or 99.5% by volume of C<sub>2</sub>H<sub>5</sub>OH. (*Id.* at 116). Therefore, the Court adopts Plaintiffs' construction.

#### **IV. CONCLUSION**

Within five days the parties shall submit a proposed order consistent with this Memorandum Opinion.